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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,258	12/12/2003	Giorgio Soldani	023349-00285	8654

7590 10/05/2006  
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EXAMINER

YAO, SAMCHUAN CUA

ART UNIT PAPER NUMBER

1733

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/733,258

Applicant(s)

SOLDANI, GIORGIO

Examiner

Sam Chuan C. Yao

Art Unit

1733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-15 is/are rejected.
- 7) ☒ Claim(s) 11 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 08-02-04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group I (claims 1-15 and 22) in the reply filed on 08-16-06 is acknowledged.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 6, 9-10 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Soldani (US 5,387,621).

Soldani discloses a system for making a tubular porous membrane, which is suitable for medical applications such as vascular prostheses, the system comprises:

- a) a polymer solution including a natural or synthetic polymer and solvent, and a non-solvent for the polymer, the non-solvent including a water containing substance such as alkanol;
- b) an apparatus including
  - i) a rotating supporting mandrel;
  - ii) a bidirectionally moving carriage disposed adjacent to the mandrel moving in parallel relative to the mandrel, and further wherein a pair of spray guns are

mounted therein to separately but simultaneously spray the polymer solution and the non-solvent onto the rotating mandrel;

iii) a mixing chamber for each spray gun (col. 2 lines 25-40; col. 3 lines 1-19; col. 4 lines 41-64; col. 5 line 41 to col. 6 line 36).

Though not explicitly disclosed, the mixing chambers must inherently be disposed upstream from the spray-guns in order to supply a polymer solution and a non-solvent to the spray guns by flowing them from the source through a conduit to the spray guns. In any event, such would have been obvious in the art as such is an art recognized effective way for providing a fluid mixture and delivering it to a spray means.

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soldani (US 5,387,621) as applied to claim 1 above.

Soldani teaches that "the degree of porosity of membrane can be varied by adding different amount of nonsolvents or by using nonsolvents of differing chemical compositions to the polymeric solution." (col. 3 lines 25-35; col. 4 lines 24-30). Additionally and more important, Soldani discloses suitable ranges of concentration for the polymer solution and the nonsolvent (Table 1). It would have been obvious in the art to provide a controller to the mixing means in Soldani as such is an art recognized effective and convenient way for automatically varying the concentration in a solution to a desired preset concentration by controlling the amount of feed components to be added into a mixing means.

5. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soldani (US 5, 387,621) as applied to claim 1 or 3 above, and further in view of Cline et al (US 6,161,723).

It would have been obvious in the art to provide a pump for supplying the solutions to the sprayers in a system of Soldani as such is an art recognized way for supplying a fluid to a spraying means at a desired fluid pressure as exemplified in the teachings of Cline et al (col. 5 line 4 to col. 6 line 6; figure 1). As for the limitation in claim 5, see column 6 lines 17-22 of the Soldani patent, where a pressurized nitrogen gas is connected to the solution. Additionally, Cline et al also teaches incorporating a pressurized gas to a dispensing solution in a sprayer to obtain an appropriate spraying characteristic (col. 16 lines figure 27). It would have been obvious in the art to connect pressurized gas to the solutions in order to provide an appropriate spraying flow characteristic.

6. Claims 7-8 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soldani (US 5,387,621) as applied to claim 1 above, and further in view of Chouinard (US 6,709,455).

With respect to claims 7 and 13-15, it would have been obvious in the art to provide a stent onto a tubular mandrel of Soldani before a spraying operation is performed in forming a membrane, because Chouinard, drawn to a process for making implantable article of the type suggested by Soldani, discloses the desirability for making a stent-graft-membrane (hereinafter simply referred to as SGM) for medical applications such as "intravascular treatment of stenoses,

aneurysms or fistulas", and suggests providing a stent onto a tubular mandrel, spraying a solution onto the stent to form a membrane on the stent, and then providing a graft onto the membrane (col. 1 lines 9-17; col. 2 lines 21-39; col. 7 lines 9-13; col. 7 line 43 to col. 9 line 63; figures 4-4A). Additionally, Chouinard also discloses forming a stent by helically winding filaments (col. 8 lines 11-41) around a rotating mandrel. It would have been obvious in the art to provide a means for helically winding filaments in a system of Soldani in order to enable one to form a stent in-situ in a system of Soldani, thereby obviating the need to manufacture the stent in a different manufacturing line or buy it from a different manufacturer. It directly follows that since: a) a tubular stent naturally provides stiffening property to a tubular membrane for use as a vascular prosthesis, and b) the modified system of Soldani is capable of simultaneously helically winding filaments and spraying solutions onto a rotating mandrel (all that would have been needed is to concurrently activate the winding and spraying means), the limitations in claims 13-15 would have been obvious in the art. Note that, these claims do not positively require forming a membrane where a stiffening filament is inserted in the membrane.

With respect to claim 8, see column 9 lines 44-48 of the Chouinard patent, where it discloses a sprayed SGM on a mandrel is heated in an oven (i.e. heating element) for a desired period of time. Since the oven is capable of heating "a given zone (48) close to the stent", the limitation in this claim fails to define over the oven heater taught by Chouinard.

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***Allowable Subject Matter***

7. Claims 11 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sam Chuan C. Yao whose telephone number is (571) 272-1224. The examiner can normally be reached on Monday-Friday with second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Richard Crispino can be reached on (571) 272-1171. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Sam Chuan C. Yao  
Primary Examiner  
Art Unit 1733

Scy  
09-29-06